UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456
	Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO ALL CLASS ACTIONS	Judge Patti B. Saris

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO HOFFMAN-LA ROCHE INC.'S MOTION FOR A CONTINUED STAY OF DISCOVERY

REDACTED VERSION

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I. INTRODUCTION

Hoffman La Roche Inc.'s ("Hoffman") motion for a continued stay of discovery despite this Court's clear ruling allowing further discovery at the November 21, 2003 hearing, is a complete rehash of the 9(b) argument already before the Court. Hoffman presents no unique circumstances justifying a stay. As to Hoffman, plaintiffs complied with the Court's May 13 Order. Thus, the AMCC sets forth the general AWP scheme and then as to Hoffman as it does for every other defendant, it identifies "the specific drug or drugs that were purchased from the defendant [and] the allegedly fraudulent AWP for each drug," as required by the Court's May 12, 2003 Order. As explained in the voluminous briefing, and in response to the 23 separate memoranda which also raised this issue, plaintiffs have complied with 9(b) as applied by this Circuit in RICO cases where the fraud has occurred over a long period, and involves multiple acts the details of which have been actively concealed by defendants. The recent decision in *In re Lupron Mktg. & Sales Practices Litig.*, MDL No. 1430 (D. Mass. Nov. 20, 2003) fully supports plaintiffs' position that the AMCC satisfies 9(b) and belies Hoffman's argument that a stay is appropriate because its motion is a "likely winner." In *Lupron* the court denied motions to dismiss RICO and state law claims arising out of the AWP scheme implemented by Abbott, TAP and others with respect to the drug Lupron. In doing so, the *Lupron* court rejected arguments identical to those now before the Court.

Thus, the Court should deny Hoffman's motion for a stay which ignores: (1) the Court's May 13 Order specifying what type of detail was to be provided; (2) the allegations of the complaint which establish the general scheme; and (3) reasonable inferences that can be drawn from the detail in the complaint that are completely ignored by Hoffman. Indeed, as set forth below, and as alleged by the AMCC, one of Hoffman's drugs, Kytril, has been the subject of extensive AWP manipulation well documented in the complaint when it was manufactured and distributed by SmithKline Beecham ("SKB"). When Hoffman obtained the rights to Kytril, it did not decrease Kytril's

inflated and phony AWP, but maintained the spread that had been established as a result of SKB's spread scheme. It did so to remain competitive with GSK's Zofran, another drug with respect to which the AMCC documents AWP manipulation. *See, e.g.*, ¶¶ 386-412. Given this history, it is reasonable to infer from the AMCC that Hoffman has engaged in the same AWP scheme outlined in the AMCC. Finally, should the Court conclude additional specificity is needed, the Court should permit discovery to proceed pursuant to *New England DataServices, Inc. v. Becher*, 829 F.2d 286 (1st Cir. 1987).

II. ARGUMENT

A. Plaintiffs Have Adequately Alleged the Circumstances of the Fraud with Respect to Hoffman

1. The Relevant Legal Framework

Consistent with this Court's ruling in *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 46 (D. Mass. 2001), Plaintiffs have "allege[d] the circumstances of the fraud" but are "***not*** required to plead ***all*** of the evidence or facts supporting it." *Id.* at 46-47 (emphasis added); *see also id.* at 46 ("The requirements of Rule 9(b) . . . must be read in conjunction with Fed. R. Civ. P. 8(a)," which requires only a "short and plain statement of the claim."). Indeed, the Court has recognized that "where the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible." *Id.* at 49.

The *Parke-Davis* ruling is in accord with other decisions from this District, including *In re Xcelera.com Sec. Litig.*, 2002 U.S. Dist. Lexis 7400, at *7-8 (D. Mass. Mar. 8, 2002), where Judge Zobel applied Rule 9(b) and sustained plaintiffs' securities fraud claim because the complaint cited to nine investigative sources and identified and quoted from "supporting documentation to buttress the[] allegations;" and Senior Judge Caffrey's decision in *Kuney Int'l, S.A. v. DiIanni*, 746 F. Supp. 234, 237 (D. Mass. 1990), where the Court commented that Rule 9(b) is satisfied where "[t]he general outline of the general scheme to defraud . . . provides the defendant with notice of the grounds on

which the plaintiff's claim is based."

2. The Complaint Satisfies 9(b) Under First Circuit Authority and the *Lupron* Decision

In the *Lupron* litigation, plaintiffs brought claims against Abbott Laboratories and others alleging violations of RICO and state law arising out of the same AWP scheme at issue here.

Defendants moved to dismiss claiming that plaintiffs have failed to "set forth the time, place, content, or individuals responsible for the mail or wire fraud" and rely instead on "generic assertions that marketing, sales and other documents were disseminated by wire." *Lupron* at 20.

The *Lupron* court found that the complaint, which is similar to the AMCC, satisfied 9(b):

> [T]he Amended Complaint alleges a course of protracted conduct on the defendants' part that virtually spanned the ten years from the introduction of Lupron® to the American market to TAP's guilty plea in 2001. It is true, as defendants contend, that the Amended Complaint does not identify specific instances of mailings, or the use of facsimile transmissions, or the telephone. But the Amended Complaint is reasonably specific as to the nature of the materials that are alleged to have been distributed in furtherance of the scheme. *See, e.g.*, Consolidated Complaint ¶ 88 (1996 fraudulent marketing materials), ¶ 108 (1995 fraudulent sales directives), ¶ 150 (national marketing and sales plans). More particularly ¶ 151 specifies eight categories of documents that are alleged to have been disseminated by mail or wire in furtherance of the scheme, including: (1) marketing materials promoting the AWP spread; (2) the submissions of the AWP to the *Red Book*; (3) communications related to the distribution of free samples; (4) inaccurate credit memos and invoices sent to physicians; (5) communications regarding junkets and the TAP into the Future program; (6) communications with government agencies misrepresenting the AWP; (7) similar misleading communications with patients and health insurers; and (8) the receipt of payments for Lupron®.[1]

[1] *Lupron* at 22 (footnote omitted).

The AMCC makes nearly identical types of allegations. The AMCC identifies the nature of the materials alleged to be part of the AWP scheme in the same general fashion as did the *Lupron* plaintiffs. *See, e.g.*, ¶¶ 160-63 (publication of AWPs), ¶¶ 164-66 (free samples), ¶ 167 (inducements), ¶¶ 170-78 (secret deals with PBMs), ¶¶ 191-96 (concealment of the scheme). And, as did the plaintiffs in *Lupron*, the AMCC at ¶ 666 then identifies nine categories of documents used to further the scheme:

> (a) Marketing materials about the AWPs for brand name drugs and the available spread, which were sent by the Defendant Drug Manufacturers to PBMs (including Medco Health) located across the country;
>
> (b) Written representations of the AWPs made by the Defendant Drug Manufacturers to the Publishers, which were made at least annually and in many cases several times during a single year;
>
> (c) Thousands of written and oral communications discussing, negotiating and confirming the placement of a Defendant Drug Manufacturer's drugs on a particular PBM's formulary;
>
> (d) Documents providing information or incentives designed to lessen the prices that each of the PBMs paid for drugs, and/or to conceal those prices or the AWP Scheme;
>
> (e) Written communications, including checks, relating to rebates, kickbacks or other financial inducements paid to each of the PBMs to persuade them to advocate one Defendant Drug Manufacturers' drug over a drug manufactured by a competitor;
>
> (f) Written and oral communications with U.S. Government agencies and private insurers that fraudulently misrepresented what the AWPs were, or that were intended to deter investigations into the true nature of the AWPs or to forestall changes to reimbursement based on something other than AWPs;
>
> (g) Written and oral communications with health insurers and patients;
>
> (h) Receipts of money on tens of thousands of occasions through the U.S. mails and interstate wire facilities – the wrongful proceeds of the Defendant Drug Manufacturers' AWP Scheme; and

> (i) In addition to the above-referenced RICO predicate acts, Defendants' corporate headquarters have communicated through use of the U.S. mails and by interstate wire facilities with their various local headquarters or divisions, in furtherance of the AWP Scheme.

Thus, the AMCC has at least the same level of particularity if not more than that deemed sufficient in *Lupron*. And, in fact, there is more to the AMCC allegations regarding Hoffman as described below.

3. The AMCC Allege Competition Based Upon Aggressive AWP Manipulation

Here, the "circumstances of the fraud" and the "general outline of the general scheme to defraud" have been alleged. Plaintiffs have with respect to Hoffman alleged precisely what was required by the May 13 Order, by identifying the drugs at issue and the inflated AWPs. Hoffman based its motion on the purported grounds that the AMCC does not provide specific details as to Hoffman's AWP abuse.

Hoffman's motion ignores the reasonable inferences and details that can be drawn from the complaint, as evidenced by focusing on the allegations as to just one drug, Kytril.

Kytril was originally developed by SKB and competed with Glaxo's Zofran. These two companies merged to become GSK. As a condition of approval of the merger, the FTC required GSK to divest its rights to Kytril and they were acquired by Hoffman. Hoffman's Kytril now competes with GSK's Zofron. As ***detailed*** in the AMCC, Zofran and Kytril, prior to Hoffman's acquisition of Kytril, competed based on the AWP spread and inflated AWPs and continue to do so after the merger. *See, e.g.*, ¶¶ 386-412.

The AMCC documents how Glaxo and SmithKline competed based on AWP manipulation and the resulting spreads. For example, in February 1995, the *Florida Infusion Chemo Net* reported that Glaxo was increasing the published AWP for Zofran®, but was specifically offering incentives to lower the actual price offered to medical providers, thereby allowing medical providers to seek reimbursement at inflated prices.

Specifically:

> Effective January 3, 1995. Glaxo has increased the acquisition costs of Zofran injection. The new AWP is set at $233.02. However, the company has provided incentives to the market place which will ensure that Zofran price to physicians and clinics will be lower than the contractual price available prior to the increase.

Letter from Bliley, Chairman Commerce Committee to Nancy Min DeParle, Sept. 25, 2000 (P007015-P007490, at P007046). ¶ 392.

In March 1996, Glaxo again increased the AWP for Zofran® by 4.8%. In response, SKB immediately increased the AWP for Kytril by 4.8%. An internal SKB memo, dated March 21, 1996, entitled "Kytril Price Increase," states:

> I recommend a 4.8% price increase effective March 25, 1996 for all Kytril presentations. This is in response to a Glaxo Wellcome price increase of 4.8% for Zofran effective March 8, 1996.

(P007015-P007490, at P007078). ¶ 394.

In marketing the new Zofran® premixed IV bag, Glaxo produced and used a document entitled "Profit Maximization – It's In the Bag." This document compared Kytril® to Zofran® based upon its total return of investment (ROI). Specifically, Glaxo's marketing materials including the following chart:

	Cost	AWP	Potential Reimbursement/ Patient	Reimbursement/ Year	ROI
Zofran 32mg bag	$110.41	$195.00	84.59	$13,957,350	76.6%
Kytril 1 mg vial	$102.73	$175.00	72.27	$11,924,000	70.3%

(P007114) (Highly Confidential). ¶ 398.

In a September 27, 2000 article in *USA Today,* Glaxo spokesman Rick Sluder discussed the issue of the spread and blamed a system that set up a reimbursement method that relies on average wholesale prices which are not actually "representative of actual prices." Mr. Sluder, admitting that Glaxo changed its wholesale prices to keep up

with competitors who changed wholesale prices, stated "We didn't want to put ourselves at a price disadvantage." One competitor he was referring to was SmithKline and Kytril. Mr. Sluder also admitted that the marketing of Glaxo drugs is based, in part, on the spread. In fact, he noted that Glaxo's sales staff is briefed on the price advantages to doctors who bill and get reimbursed based upon the AWP. (E-mail from Clapton to Vaughan dated Sept. 27, 2000 citing "How Drug Makers Influence Medicare Reimbursements to Doctors; WALL STREET JOURNAL (P007501-P007506)). ¶ 401.

Meanwhile, SKB was competing based on the spread as well.

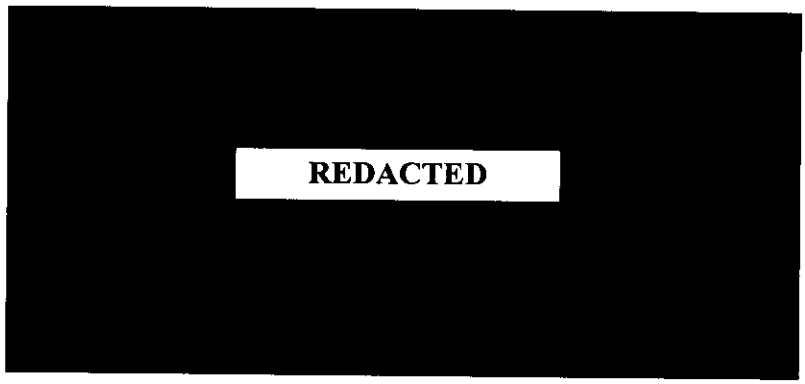
Internal SKB documents reveal how it marketed the spread. One internal document entitled "Price Comparison of Kytril and Zofran for Reimbursement" discussed how much additional revenue and "spread per patient" a medical provider would make by using Kytril® due to its larger spread. It stated:

> Kytril reimbursement for 5 patients treated $540.00 - Kytril 6 treated patients $423.12
>
> Difference = $117.00 every 6 patients.
>
> Use 5ht3 5 times a day = $2,340.00 month. $28,080.00 year more!

(P007015-P007490, at P007117.) ¶ 403.

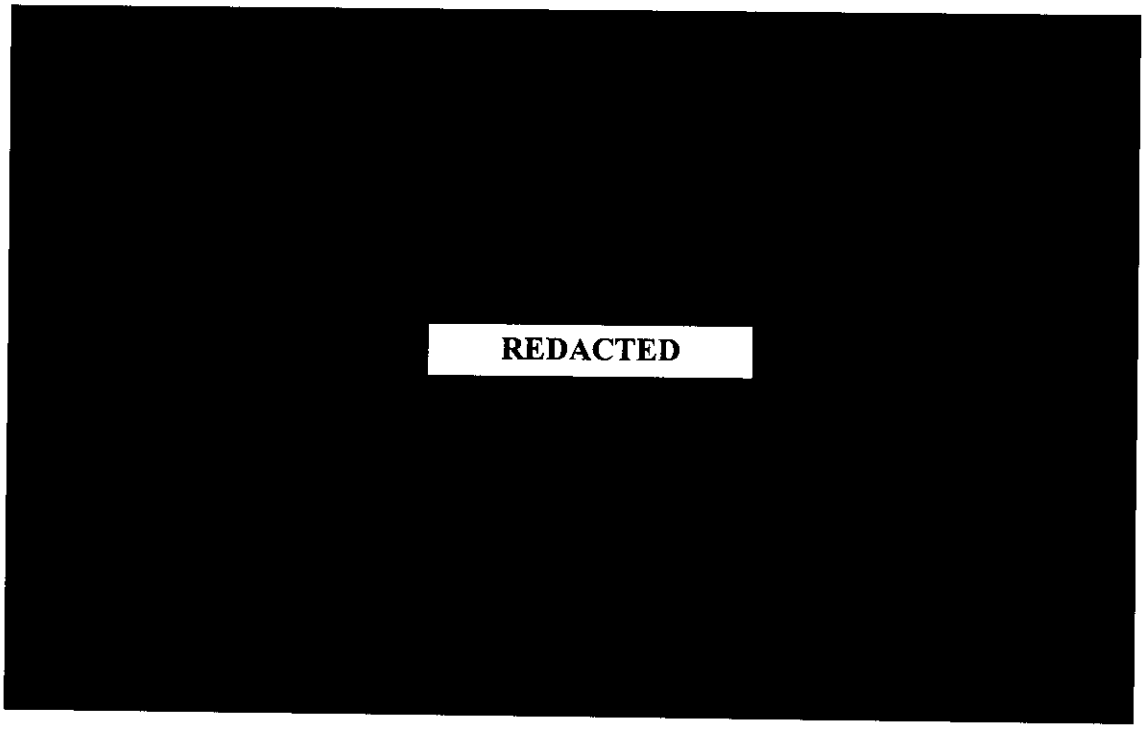
The AMCC alleges that other internal SKB documents entitled "Cost v. Profit" and "Kytril Profit Model" compare Kytril® and Zofran® to demonstrate how much additional profit/revenue the medical provider will receive by using Kytril®. Plaintiffs did not cite chapter and verse of these documents, but they could have. For example, SmithKline ran a promotion aggressively pitching the "reimbursement spread" per patient of [REDACTED] (*See* GSK-MDL-ZNO1-057682, attached as Exhibit A.) And it aggressively increased AWP, while providing secret "chargebacks" and "rebates" to wholesalers. (*See* GSKMDL-ZNO1-057685, Exhibit B.) SKB created and distributed documents showing that as a result of the AWP spread, a clinic could realize a profit of

REDACTED (GSK-MDL-ZNO1-057695, Exhibit C.) And SKB prepared a document informing doctors of the "Big Picture."



(GSK-MDL-ZNO1-057702, Exhibit D.)

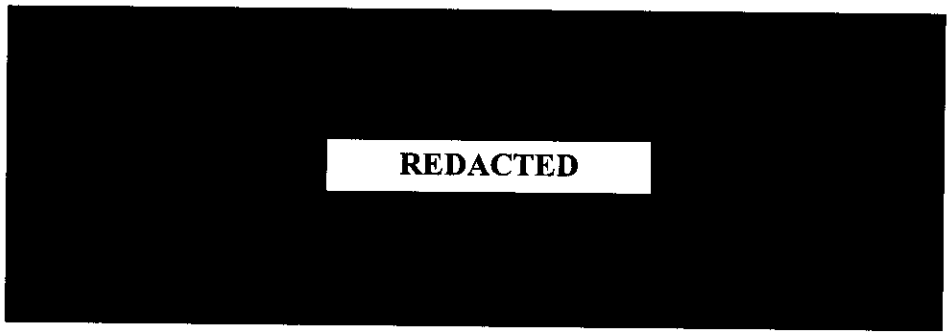
In an internal analysis, SKB, commenting on the success of its AWP scheme, observed:



(GSK-MDL-ZNO1-057702, Exhibit E.) (Emphasis added.)

In response to SKB's manipulation, GSK also launched a "clinic campaign" aggressively marketing the spread:

 RSION



(GSK-MDL-ZNO1-058240, Exhibit F.)

When Kytril was purchased by Hoffman these competitive conditions did not change and its reasonable to infer that Hoffman continued marketing of the spread or it could not compete with Zofran. This inference is reasonable given the fact that Hoffman did not lower the reported AWP, and in fact it increased slightly:

KYTRIL AWPs[2]

Dose	NDC	1997 AWP	1998 AWP	1999 AWP	2000 AWP	2001 AWP	2002 AWP	2003 AWP
SOL 1mg/ml, 1ml	00029-4149-01; 00004-0239-09	$177.40	$177.40	$186.10	$195.20	$195.20	$195.20	$195.20
SOL 1mg/ml, 4ml	00029-4152-01; 00004-0240-09	N/A	709.60	$744.35	$780.80	$780.80	$780.80	$780.80
2mg/10ml, 30ml	00004-0237-09	N/A	N/A	N/A	N/A	N/A	N/A	$271.01
TAB 1mg, 2s ea	00029-4151-39; 00004-0241-33	$85.50	$85.50	$89.70	$94.10	$94.10	$94.10	$94.10
TAB 1mg, 20s ea	00029-4151-05	$855.00	$855.00	$896.90	$940.85	$940.85	$940.85	N/A

Given the fact that the spread still exists, Hoffman has simply perpetuated the AWP scheme to remain competitive with GSK. It is, therefore, squarely within the same AWP paradigm as the other defendants and its motion should be denied.

[2] Shaded area indicates Kytril manufactured by Hoffman-La Roche as indicated by the *Red Book*. However, the segment of Kytril's NDC code that indicates its manufacturer remained SKB (00029) until 2002, when it changed to Hoffman-La Roche (00004).

B. Alternatively the Discovery is Proper Under *Becher*

Alternatively, if the Court believes that more specificity is needed, in these circumstances, *New England DataServices, Inc. v. Becher*, 829 F.2d 286 (1st Cir. 1987), suggests that discovery is appropriate and that the stay motion should be denied.

In *Becher*, the court held that "Rule 9(b) requires specificity in the pleading of RICO mail and wire fraud," but that dismissal should ***not*** be automatic in the event that a court determines that the plaintiff has failed to satisfy Rule 9(b). *Id.* at 290. Rather, as the First Circuit explained, the court should determine whether sufficient facts have been pled that warrant further discovery and an opportunity to amend the complaint after completion of the discovery:

> In an appropriate case, where, for example the specific allegations of the plaintiff make it likely that the defendant used interstate mail or telecommunications facilities, and the specific information as to use is likely in the exclusive control of the defendant, the court should make a ***second*** determination as to whether the claim as presented warrants the allowance of discovery and if so, thereafter provide an opportunity to amend the defective complaint.

Id. (emphasis added); *see also Ahmed v. Rosenblatt*, 118 F.3d 886, 889-90 (1st Cir. 1997) ("Rule 9(b) has a special gloss in the RICO context in cases where a plaintiff's specific allegations make it likely that a defendant has used interstate mails or wire, and where this information is in the exclusive control of the defendant: before granting a motion to dismiss, a district court should make a second determination as to whether further discovery is warranted and, if so, the plaintiff should be provided with the opportunity to amend the complaint after the completion of this discovery."); *Freeport Transit, Inc. v. McNulty*, 239 F. Supp. 2d 102, 117 (D. Me. 2002) (applying *Becher* and concluding that, "[o]n balance, Plaintiffs have outlined the contours of a fraudulent scheme, which suggests a fair probability that the details can be uncovered in discovery"), *aff'd in part*, 239 F. Supp. 2d 102 (D. Me. 2003); *Overton Corp. v. Case Equipment Co.*, 1990 U.S. Dist. Lexis 18275, at *13 (D. Me. Dec. 20, 1990) ("The plaintiffs have outlined the

general scheme employed to defraud them. . . . Discovery as to when the wires and mails were used and what was communicated by defendants . . . will either produce the facts needed to bring this complaint into compliance with Rule 9 or make clear to the plaintiffs that their asserted claim does not lie.").

In making the so-called "*Becher* second determination," the court balances a number of factors, including allegations of the general scheme to defraud, the establishment of interstate commerce and the resulting implication of the use of interstate wires and mails, and whether the facts were "peculiarly" within the defendants' control. 829 F.2d at 291-92. The First Circuit also counsels courts to be mindful of Rule 9(b)'s purpose to weed out groundless claims and provide defendants with an adequate opportunity to supply meaningful responses, yet "the court should note the policy in favor of allowing amendments and trying cases on their merits, and against dismissals which would deny plaintiffs their day in court." *Id.* at 292 (citing *United States v. Hougham*, 364 U.S. 310, 317 (1960)).

In applying these factors here, the Court should find that the additional discovery sought by plaintiffs is warranted. Plaintiffs have alleged the general scheme to defraud in great detail, citing to various governmental investigations and many specific documents. Thus, it is clear that plaintiffs' claims do not offend Rule 9(b) principles, and that the discovery sought is not part of a stereotypical "fishing expedition" designed to support allegations that are otherwise baseless. Plaintiffs have alleged a fraudulent AWP for Hoffman's drugs and cited details of AWP manipulation with respect to one such drug and that Hoffman continued the phony AWP when it acquired Kytril. Hoffman has not

been subject to discovery or investigation and thus has been able to conceal the documents which would provide the specificity it now demands. Hoffman's motion should be denied, but at a minimum, *Becher* discovery is warranted here.

DATED:

By_____

Thomas M. Sobol (BBO#471770)
Edward Notargiacomo (BBO#567636)
Hagens Berman LLP
225 Franklin Street, 26th Floor
Boston, MA 02110
Telephone: (617) 482-3700
Facsimile: (617) 482-3003
LIAISON COUNSEL

Steve W. Berman
Sean R. Matt
Kevin P. Roddy
Hagens Berman LLP
1301 Fifth Avenue, Suite 2900
Seattle, WA 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594

Samuel Heins
Heins, Mills & Olson, P.C.
3550 IDS Center
80 South Eighth Street
Minneapolis, MN 55402
Telephone: (612) 338-4605
Facsimile: (612) 338-4692

Eugene A. Spector
Spector, Roseman & Kodroff, P.C.
1818 Market Street, Suite 2500
Philadelphia, PA 19103
Telephone: (215) 496-0300
Facsimile: (215) 496-6611
CHAIRS OF LEAD COUNSEL COMMITTEE

Marc H. Edelson
Hoffman & Edelson
45 West Court Street
Doylestown, PA 18901
Telephone: (215) 230-8043
Facsimile: (215) 230-8735

Kenneth A. Wexler
Elizabeth Fegan Hartweg
The Wexler Firm
One North LaSalle Street, Suite 2000
Chicago, IL 60602
Telephone: (312) 346-2222
Facsimile: (312) 346-0022
MEMBERS OF LEAD COUNSEL COMMITTEE AND EXECUTIVE COMMITTEE

Michael McShane
Alexander, Hawes & Audet, LLP
300 Montgomery Street, Suite 400
San Francisco, CA 94104
Telephone: (415) 982-1886
Facsimile: (415) 576-1776

Robert E. Piper, Jr.
Piper & Associates
624 Pierre Avenue
Shreveport, LA 71103
Telephone: (318) 226-0826
Facsimile: (318) 424-9900
MEMBERS OF EXECUTIVE COMMITTEE

Anthony Bolognese
Bolognese & Associates
One Penn Center
1617 JFK Boulevard
Suite 650
Philadelphia, PA 19103
Tel: (215) 814-6750
Fax: (215) 814-6764

Jonathan W. Cuneo
The Cuneo Law Group
317 Massachusetts Avenue, N.E.
Suite 300
Washington, D.C. 20002
Tel: (202) 789-3960
Fax: (202) 789-1813

Neal Goldstein (Of Counsel)
Freedman & Lorry, PC
400 Market Street, Suit 900
Philadelphia, PA 19106
Tel: (215) 925-8400
Fax: (215) 925-7516

Michael E. Criden
Hanzman & Criden, PA
Commerce Bank Center, Suite 400
220 Alhambra Circle
Coral Gables, FL 33134
Tel: (305) 357-9000
Fax: (305) 357-9050

Blake M. Harper
Kirk B. Hulett
Hulett Harper LLP
550 West C Street
Suite 1700
San Diego, CA 92101
Tel: (619) 338-1133
Fax: (619) 338-1139

Jonathan D. Karmel
Karmel & Gilden
221 N. LaSalle Street
Suite 1414
Chicago, IL 60601
Tel: (312) 641-2910
Fax: (312) 641-0781

Dianne M. Nast
Roda & Nast, PC
801 Estelle Drive
Lancaster, PA 17601
Tel: 717-892-3000
Fax: 717-892-1200

Henry H. Rossbacher
Rossbacher & Associates
811 Wilshire Boulevard,
Suite 1650
Los Angeles, CA 90017-2666
Tel: (213) 895-6500
Fax: (213) 895-6161

Jonathan Shub
Sheller, Ludwig & Badey, P.C.
1528 Walnut Street, 3rd fl
Philadelphia, PA 19102
Tel: (215) 790-7300
Fax: (215) 546-0942

Scott R. Shepherd
Shepherd & Finkleman, LLC
117 Gayley Street,
Suite 200
Media, PA 19063
Tel: (610) 891-9880
Fax: (610) 891-9883

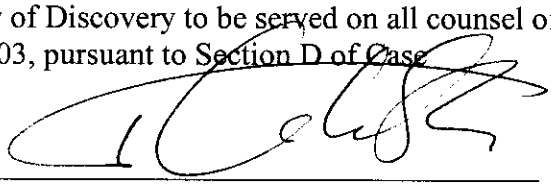
Lisa J. Rodriguez
Ira Neil Richards
Trujillo Rodriguez& Richards, LLC
The Penthouse
226 West Rittenhouse Square
Philadelphia, PA 19103
Tel: (215) 731-9004
Fax: (215) 731-9044

Mitchell A. Toups
Weller, Green, Toups & Terrell, L.L.P.
2615 Calder Street, Suite 400
P.O. Box 350
Beaumont, TX 77704
Tel: (409) 838-0101
Fax: 409-838-6780

Damon Young
Lance Lee
Young, Pickett & Lee
4122 Texas Boulevard
P.O. Box 1897
Texarkana, AR/TX 75504
Tel: (903) 794-1303
Fax: 903-792-5098; 903-794-5098
ADDITIONAL ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that I, Thomas M. Sobol, an attorney, caused a true and correct copy of the foregoing Plaintiffs' Memorandum in Opposition to Hoffman-La Roche Inc.'s Motion for a Continued Stay of Discovery to be served on all counsel of record electronically on December 19, 2003, pursuant to Section D of Case Management Order No. 2.



Thomas M. Sobol, Esq.
HAGENS BERMAN LLP
225 Franklin Street, 26th Floor
Boston, MA 02110
Telephone: (617) 482-3700